

Feasibility of Translating Laboratory Findings into Dietary Routines: Omega-3 Fatty Acids Regimen in

High Risk Breast Cancer Women

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Abstract

Family history, abnormal pathology related to breast biopsy, and/or personal history of breast cancer are factors that place women at highest risk for breast cancer development. Animal studies using omega 3 fatty acid supplementation have demonstrated a protective effect on breast tissue. At this institution, an IRB-approved study is ongoing to measure the effects of increased dietary intake of fish rich in omega 3 fatty acids versus omega 3 supplementation on breast adipose and serum fatty acid profiles. As a corollary to this study, a 13-item self-report questionnaire was developed for administration at the end of the study period to measure patient-reported outcomes, patient patterns and overall patient satisfaction with the intervention. The objective of this questionnaire was to evaluate the patients' perspectives of their participation in the study and how likely they might be to continue the proposed regimen given positive study outcomes. Interim examination of the data demonstrated complaints of brief periods of symptoms, such as 'upset stomach' and 'headache' among the first participants to complete the study. Several participants reported a feeling of accomplishment. When asked if they could sustain a diet with multiple servings of omega 3 rich fish per week, participants indicated that it would be difficult. Innovative recipes or inclusion of formal dietary guidance may be helpful. These limited findings address the importance of patient-reported outcomes that may help individualize and tailor preventive interventions into daily living.

Feasibility of Translating Laboratory Findings into Dietary Routines: Omega-3 Fatty Acids Regimen in High Risk Breast Cancer Women

Introduction

Cancer has evolved into a public health crisis that disrupts the lives of more than 1.4 million Americans diagnosed each year (Sardo, 2011). The U.S. economy spends more than \$305 billion a year on cancer. Therefore, an emphasis on cancer prevention is becoming embedded in our healthcare industry (Sardo, 2011). In 2008, a document entitled the *National Call to Action on Cancer Prevention and Survivorship*, was released that addressed various strategies for the fight against cancer. The report provided recommendations regarding ideal dietary habits for cancer prevention and survivorship (Zenzano, Allan, Bigley, Bushardt, Garr, et al., 2011). Research demonstrates that diet may be accountable for approximately 30% of cancer occurring in Western countries (McLaughlin, Olivo-Marston, Vitolins, et al., 2011; World Health Organization, 2003). Epidemiological studies about food and nutrition support the potential hope that cancer incidence and death can be decreased with proper diet and other lifestyle modifications such as increased physical activity (Ross, 2010). Differences in dietary intake among individuals may be responsible for significant increases in cancer incidence (Sansbury, Wanke, Albert, et al., 2009). Therefore, a collaborative and multidisciplinary effort from health care professionals is needed to embrace a patient-centered approach that encompasses potential factors and risks that may impact a cancer-free life for a particular individual (Sardo, 2011).

The increased intake of nutrients has immense potential to guide cellular behavior and prevent unwanted variation. The impact of health promotion efforts, such as a healthy diet can have positive effects on daily living and overall quality of life. Countless studies are underway in hopes of identifying specific compounds found in daily food components that act as instigators or protectors against chronic diseases, especially cancers (McLaughlin, Olivo-Marston, Vitolins, et al., 2011). For example, omega 3 fatty acids, most heavily found in fish oil, regulate inflammatory and immune responses throughout the body and, in turn, may play a role in cancer prevention for at-risk and high risk populations (Larsson,

Kumlin, Ingelman-Sundberg, & Wolk, 2004; MacLean, Newberry, Mojica, Khanna, Issa, et al., 2006; Wall, Ross, Fitzgerald, & Stanton, 2010).

In spite of exciting discoveries that allow researchers to grasp a deeper understanding of the molecular level of cancer control, gaps exist in the application of these discoveries to cancer prevention in the clinical setting (Ross, 2010). Existing studies show evidence of certain food constituents serving as preventative measures to ward off cancer onset and growth. Importantly, the study design including the food constituent and total regimen must be closely monitored to ensure patient adherence and measures of satisfaction with the proposed intervention (Ross, 2010).

The health promotional effects promoted by these studies include a healthy diet, ideal body weight and physical activity. These healthy behaviors must be integrated in the models of practice of every health professional, especially nurses (Sardo, 2011; Zenzano, et al., 2011). Interdisciplinary teams should collaborate to devise realistic care plans for implementation in the hectic lifestyles of individuals (Sardo, 2011; Zenzano, et al., 2011).

Animal studies using omega 3 fatty acid supplementation have demonstrated a potential effect on breast tissue. At this institution, an IRB-approved study is ongoing to measure the effects of increased dietary intake of fish rich in omega-3 fatty acids versus omega-3 supplementation on breast adipose and serum fatty acid profiles. In order to evaluate the participants' perspectives of goal attainment and their perceived ability to adhere to the proposed regimen over time, an exit survey is administered during their last appointment. The survey consists of a 13-item self-report questionnaire featuring open- and close-ended items, with Likert-type responses in order to measure patient-reported outcomes, examine patient adherence, and gauge overall satisfaction with the intervention. The goal of this study objective is to evaluate the patients' perspectives of their dietary intake of fish versus fish oil capsules and how likely they are to continue the proposed regimen after completion of the study.

Significance and Literature Review

Studies in animals

Due to their crucial functions related to cell membrane flexibility and bound enzymes, polyunsaturated fatty acids including omega-3 and omega-6 play critical roles in blood pressure, blood clotting, brain and nervous system functioning, altered estrogen metabolism, suppression of arachidonic acid and gene expression (Larsson, Kumlin, Ingelman-Sundberg, & Wolk, 2004; Wall, Ross, Fitzgerald, & Stanton, 2010). Polyunsaturated fatty acids produce lipid mediators called eicosanoids that directly regulate inflammatory and immune responses throughout the body, including platelet aggregation and cellular growth (Larsson, Kumlin, Ingelman-Sundberg, & Wolk, 2004; Wall, Ross, Fitzgerald, & Stanton, 2010). Most heavily found in fish oil, the omega-3 fatty acids help prevent and treat coronary artery disease, diabetes, hypertension, arthritis and cancer (Stapleton, Martin, & Mayer, 2010). These omega-3 fatty acids are needed for normal development and function, especially within the cell membranes of the brain and eye (Stapleton, Martin, & Mayer, 2010). When mice with acute lung injury were given omega-3 fatty acids through endogenous synthesis or intravenous infusion, decreased edema formation, leukocyte infiltration and overall malaise were evident (Stapleton, Martin, & Mayer, 2010). A study also documented the relationship between omega-3 fatty acid intake and the prevention of myocardial infarction, diabetes, hypertriglyceridemia and various autoimmune disorders (Stapleton, Martin, & Mayer, 2010). A study focusing on a single facility's cardiac surgical patients found an association between oral administration of omega-3 fatty acids and a reduction in postoperative atrial fibrillation which led to a shorter length of stay in the hospital (Stapleton, Martin, & Mayer, 2010).

Multiple animal and in vitro studies are bringing forth evidence reiterating the importance of omega-3 fatty acids, especially the long-chain eicosapentaenoic acid and docosahexaenoic acid, and their ability to conquer carcinogenesis (Larsson, Kumlin, Ingelman-Sundberg, & Wolk, 2004). Daily intake of eicosapentaenoic acid and docosahexaenoic acid has shown to decrease tumor growth and metastasis of human breast cancer grafts in mice (Yee, Lester, Cole, Richardson, Hsu, et al., 2010). In a six month randomized trial involving 48 women at high risk of breast cancer and the administration of several varying doses of an omega-3 fatty acid supplement, levels of eicosapentaenoic and docosahexaenoic acid increased in serum and breast adipose tissue with all doses of the supplement (Yee, et al., 2010). The

omega 3- fish oil supplement indicated a low side effect profile in this study with no significant changes in platelet function and BMI (Yee, et al., 2010). The majority of patients enrolled in this study experienced no change or decreased LDL cholesterol and a slight increase in alanine transaminase (Yee, et al., 2010).

The existing epidemiologic studies examining dietary intake of fish and marine omega-3 fatty acids and the development of cancer in high risk populations have been inconclusive (Larsson, et al., 2004). Animal studies involving rodents have shown mammary tumor formation and proliferation regulated by the increase of dietary omega-3 fatty acids (MacLean, Newberry, Mojica, Khanna, Issa, et al., 2006). Another study noted an inverse association that was not statistically significant (Larsson, et al., 2004). One reason for these conflicting results may be related to the focus on total fish intake rather than simply the species of fish that contain the highest levels of omega-3 fatty acids (Larsson, et al., 2004). Since most of the evidence in regard to mechanism of action is found in research with animals, further studies are needed to adequately evaluate the effects on the clinical outcomes of humans (Stapleton, Martin, & Mayer, 2010).

Studies in humans

In addition to polyunsaturated fatty acids, researchers are identifying other food products and dietary regimens as potential aids in those at high risk for developing cancer. Dietary modifications involving tomato products and/or a soy supplement was the focus of a study seeking to identify chemopreventive agents for breast cancer in post-menopausal women (McLaughlin, Olivo-Marston, Vitolins, Bittoni, Reeves, et al., 2011). In the 26 week study, patient adherence to the proposed diet was measured by biochemical means through blood and urine levels, completion of daily worksheets and package counts. The results show that a tomato-rich diet had little effect on the biomarkers linked with breast cancer risk and the consumption of soy supplements showed a statistically significant decrease in elements that have been hypothesized to promote cancer (McLaughlin, et al., 2011). Adherence was measured by both dietary calendars and biomarker confirmation rather than subjective participant responses. Noted limitations of this study include the fact that no information was collected to evaluate

how the participant's diets were altered to compensate for the increase of tomato and soy supplements (McLaughlin, et al., 2011).

A study examining the implementation of a high-fiber, high-fruit and -vegetable and low-fat eating pattern on the incidence of adenoma recurrence in colorectal cancer shows consistent lack of effect (Sansbury, Wanke, Albert, Kahle, Schatzkin, et al., 2009). Poor dietary adherence among the participants was suggested as one reason for the unexpected results. Comparison of compliance rates separated identified three categories: inconsistent compliers (44.6%), poor compliers (29.8%) and super compliers (25.6%). When compared to the control group, the super-compliers demonstrated a statistically significant positive effect of dietary habits resulting in a decreased likelihood of multiple and advanced adenoma recurrence (Sansbury, et al., 2009).

An ongoing randomized clinical trial to examine persistent pain syndromes, specifically chronic daily headaches, and the implementation of two strict dietary interventions is ongoing (Ramsden, Mann, Faurot, Lynch, Imam, et al., 2011). The study hypothesizes that a diet low in daily oral intake of omega-6 fatty acids and high in oral omega-3 fatty acids would potentially alleviate pain and improve quality of life. Participants were required to complete self-report outcome assessments at baseline prior to the start of the trial, at their first visit after implementation of the intervention, and again at the end of the intervention. The research staff contacted participants weekly to ensure their adherence and acknowledge any concerns. A research dietitian was available throughout the study to provide focused counseling every two weeks. The patients' adherence to this dietary intervention was also aided through web-based materials that reinforced the dietitian's advice. To date, the examiners have reported excellent adherence to the daily diet regimen using these interventions (Ramsden, et al., 2011).

Clinical prevention and chronic disease management are becoming primary foci of the educational curriculums and health services delivered across the spectrum (Zenzano, et al., 2011). In attempts to reiterate the urgency of chronic disease prevention, the 2010 Patient Protection and Affordable Care Act, as well as Healthy People 2020, pushes health care professionals to reconsider their approach to improve population health activities (Zenzano, et al., 2011). In order to reach the objectives

as stated in Healthy People 2020, health professionals need to understand the roles of other professions to facilitate improved communication and collaboration among health disciplines. The foundation of nursing, which is currently the largest healthcare occupation, is rooted in clinical prevention and population health, in all the settings and specialty areas. Considered crucial to interdisciplinary practice, nurses can have a substantial impact on the health outcomes of their patients, especially when directly involved in the planning of patient care (Zenzano, et al., 2011).

Theoretical framework

A multi-disciplinary and patient-centered plan of care, as depicted in the Integrative Health Promotion Model, has proven efficient for addressing cancer prevention and survivorship. The Integrative Health Promotion Model integrates a patient's physical, mental, spiritual and emotional domains of health into their individualized plan of care. In order to accomplish this feat, education and recommended interventions provided by healthcare professionals must be collaborative, reinforced and evaluated rather than contradicted and ignored. All areas of health disciplines, including medicine, nursing, dietary, or physical therapy, must work together to help the patient manage recommended lifestyle changes to ensure success and ultimately prevent cancer (Sardo, 2011).

As outlined in the Integrative Health Promotion Model, the concept of cancer survivorship and patient outcomes relies on the relationship between patients, healthcare professionals and care planning (Sardo, 2011). For patients to adequately manage the domains of optimal health such as nutrition, physical activity, healthy weight and stress reduction, ongoing care provided by each health discipline should be evaluated against the patient's daily lifestyle to ensure successful outcomes (Sardo, 2011).

Health promotion evaluation is a process that assesses an individual's capacity to effectively and efficiently carry out an action specifically for self-improvement (Whitehead, 2002). Health promotion may be evaluated in terms of outcome measurement, which refers to what objectives have been achieved, or in terms of process evaluation that refers to how the intervention was achieved and at what cost (Whitehead, 2002). Evaluation of health promotion programs determines if an overall health gain has been met in an ethical manner (Whitehead, 2002). Thorough evaluation also serves to reveal evidence

about the intervention and infer conclusions as to how effective and realistic the implementation would be outside of a controlled research setting (Whitehead, 2002). Qualitative evaluation is most helpful to address the complexity of participants' needs and diversity and will lead to intervention modifications that will promote individualized health promotion (Van Meijel, 2003). How the participants experience the intervention and how nurses judge the feasibility of the intervention are crucial components of qualitative evaluation. A systematic and sequential approach to evaluation is essential for the future of nursing and health promotion.

Biomedical and epidemiological determined criteria are frequently used as the key measures of success in a health promotion program. When clinicians focus solely on biomedical criteria such as morbidity and mortality and disease states, care becomes problematic as other factors of wellness may be overlooked such as the patients' emotional and social well-being (Whitehead, 2002). Randomized control trials may provide strong evidence of effective and valid interventions, although they do not guarantee that the intervention will be practical for all participants (Van Meijel, 2003). Individuals who differ from the mainstream pool of participants who participated in the research study may not benefit from the proposed health promotion program (Whitehead, 2002; Van Meijel, 2003). Randomized control trials provide results that show successful effects of an intervention, not necessarily how to ensure that the intervention will be followed effectively outside of the research setting (Van Meijel, 2003).

Methods

Design

The study design is a descriptive survey questionnaire based on the randomized control trial of OSU-10024, Omega 3 Fatty Acids and Breast Cancer Prevention: Protective Benefits of Increased Fish Consumption. Patient-reported outcomes are measured at the last appointment of the study, the survey questionnaire is given to the patient to complete prior to discharge.

Summary of study

At the completion of their study period, participants are asked to complete a questionnaire that examined participants' perception of their participation, the impact of the intervention on their dietary

routine and feasibility of adherence for long-term use. This 3-month study examines the effects of increased fish consumption with randomization of patients to either dietary fish rich in omega-3 supplied in the form of canned salmon and tuna, or oral supplementation in the form of an omega-3 fatty acid capsule (Yee, Lester, Cole, Richardson, Hsu & Clinton, 2010). Participants are requested to (1) consume four 6-oz servings of canned salmon and albacore tuna or (2) take two capsules of the omega-3 fatty acid supplement daily. Measures of eicosapentaenoic acid, docosahexaenoic acid, linolenic acid, arachidonic acid and total fatty acids are obtained from breast adipose tissue samples conducted through fine needle aspirations. Monthly blood samples are obtained to examine fatty acid levels in serum to ensure compliance to the regimen.

Sample

All participants enrolled in OSU-10024: Omega-3 Fatty Acids and Breast Cancer Prevention: Protective Benefits of Increased Fish Consumption are invited to complete the exit survey questionnaire. Participants are considered at high risk for breast cancer based on various factors: “known genetic mutations associated with hereditary breast cancer, at least one first degree relative with breast cancer, two or more second degree relatives with breast cancer, prior diagnosing atypical lobular hyperplasia, atypical ductal hyperplasia, lobular carcinoma in situ or ductal carcinoma in situ in the last 10 years, a Gail Risk Assessment that is high risk compared to the general population, or prior diagnosis of T1 or T2 breast cancer diagnosed within the last 10 years” (Yee, et al., 2010). Participants must be greater than one year from pregnancy, lactation or chemotherapy, must have had a mammogram within the last twelve months, body mass index less than or equal to 30 and documented negative pregnancy test within 48 hours of study enrollment from women of childbearing age (Yee, et al., 2010). The following criteria would exclude participants from the study: concurrent metastatic malignancy, ongoing chemotherapy, history of heart disease, body mass index greater than thirty, pregnant or nursing women, breast implants, bilateral mastectomies, known sensitivity or allergy to fish, current use of anticoagulants and chronic use of omega-3 fatty acid capsules (Yee, et al., 2010). The sample, consisting of eight patients, is from a comprehensive breast clinical at a Midwestern comprehensive cancer center.

Instrument

An exit survey questionnaire was designed by the researchers based on the literature and a previous study measuring various dose levels of omega 3 oral supplementation (Yee, et al., 2010). The survey questionnaire is composed of thirteen open- and close-ended items with Likert-type responses (scale of 0-10, with 0 indicating the lowest possible response/feeling and 10 indicating the highest possible response/feeling). The questionnaire is completed during the last appointment of the study in order to measure patient-reported adherence, feasibility of continuation of assigned intervention into long-term daily routine, and overall perceived success with the assigned regimen. Questions address the participant's ability to adhere to the requirements, level of difficulty implementing into daily schedule, as well as specific questions related to each arm of the study (Appendix). Open-ended questions ask participants for recommendations on the preferred ways to prepare the dietary omega-3 fatty acids.

Results

Interim examination and analysis of data was conducted on the eight participants who have completed OSU-10024 study. Data were transcribed from the original exit survey to a Microsoft Excel spreadsheet by research personnel. Currently, eight women have completed the study; four were assigned to dietary fish and four were assigned to oral supplementation using omega-3 capsules.

The four participants assigned to dietary fish rated their feelings of accomplishment and ability to adhere to study requirements between 8 and 10. If given the opportunity to be assigned to the other arm of the study, two participants noted that they would not have preferred the omega-3 capsules. With the exclusion of one participant, all participants agreed that the dietary fish intervention was difficult to fit into their daily schedule. One participant had trouble adhering to the diet since fish was not normally a staple her diet. Among the participants assigned to dietary fish, most stated consuming canned salmon was most bothersome due to the skeleton included in the can. While the participants verbalized negative comments related to the smell of the salmon during routine appointments, only one participant documented the smell as being bothersome, especially to her family, on the survey questionnaire.

When asked to list their favorite ways to prepare the fish, the most popular responses were ‘salmon patties’ and ‘mixed with salsa or low fat mayonnaise’. Some women noted that although they were able to enjoy a salmon filet on top of mixed greens, they could not get used to canned salmon in a salad. Two of four participants on the dietary arm admitted that the study led to the incorporation of a different menu during family meals; none of these families chose to eat the required four 6-ounce servings of fish. However, during monthly follow-up phone calls, one patient explained the interest of her husband wanting to join her on this healthy diet and asked for additional cans of fish. Three out of four participants assigned to the fish arm of the study stated they could not envision long-term adherence with consumption of four 6-ounce servings of omega-3 rich fish per week. However, all four participants stated a higher confidence in their adherence if a combination of dietary fish and fish oil capsules was an option.

No adverse symptoms were reported from the women on the dietary arm of the study, although one participant reported yellowing of her hair which her hair stylist contributed to the change in her usual diet. Otherwise, the dietary fish arm of the study was well-tolerated.

The four participants randomized to fish oil capsules admitted that the regimen became routine and reasonably easy to incorporate into their schedules. Feelings of accomplishment and adherence to this end of the study ranged from 6 and 10. None of the four did not regret being assigned to omega-3 capsules. Most participants kept the bottle of capsules near their bed in order to remember their assigned daily dosage. Flatulence and headaches were the most common symptoms reported by half of the participants on the oral omega-3 supplementation arm, which subsided with the first month of the study period. Only one participant did not see herself capable of continuing the routine of taking two omega-3 capsules per day on a long-term basis.

Most of the participants provided the most detailed responses to questionnaire items that assessed the impact of the study on social functioning including family and work life. One participant documented that although she lived alone, when her family was present they would not want to consume fish. One participant assigned to the oral omega 3 supplementation arm of the study verbalized it was ‘challenging

when traveling'. Overall, participants felt a feeling of accomplishment upon completion of the study, especially since most of them exceeded their expectations.

Discussion

When examining components of health promotion utilizing increased consumption of omega 3 products in women at increased risk of breast cancer, the self-reported questionnaire survey provides information that will help individualize the plan of prevention and therefore maximize adherence patterns, feasibility and realistic practicality of the intervention. Simply because the participant is at an increased risk for breast cancer does not predetermine her desire for change, level of perseverance to succeed and capability to recover from setbacks (Bandura, 2004). As healthcare providers, nurses need to gain a greater understanding of participants' expected outcomes and perceived environmental obstacles since these factors are vital regulators of human motivation (Bandura, 2004). This survey questionnaire attempts to capture the realistic practicality of the intervention by asking participants to reflect on any unforeseen burdens or symptoms related to an increased dietary intake of fish rich in omega-3 fatty acid or oral omega-3 fatty acid supplementation.

Oral omega-3 fatty acid supplementation appears to be an easier intervention for women than increased dietary intake of fish rich in omega-3 fatty acid. Little thought or hassle is involved with oral omega-3 fatty acid supplementation; administering two capsules per day becomes routine and habitual. Participants with hectic lifestyles filled with family duties and career obligations had little to no complaints of adapting to the intervention. Although few participants experienced brief episodes of increased flatulence and minor headaches during the first few weeks of implementation, it was not severe enough to alter their adherence or overall satisfaction with the intervention.

Participants randomized to the increased dietary intake of fish rich in omega-3 fatty acids were much more passionate with their responses. Most of these participants would have rather been randomized to the oral omega 3 supplementation branch of the study. Knowing that there was an 'easier' intervention may have altered participant's self-efficacy; low self-efficacy may directly affect the participant's goal setting process, leaving them less committed to be successful with the assigned

objective (Locke & Latham, 2002). Goal setting within this trial may be solely dependent on how much fish the participant consumed on a regular basis prior to involvement with the trial. One participant voiced disappointment when assigned to oral omega-3 supplementation.

The difficulty of identifying variety in ways to prepare the required number of weekly servings of tuna and salmon was a common response from women. These potential concerns are discussed with participants at the beginning of the trial. Several small recipe booklets and dietary internet links are supplied to those participants randomized to dietary fish consumption. Although all participants received the same recipes, it would be helpful to individualize the recipe booklets based on what needs the participant may have, relevant to their personal and family characteristics, e.g., kid-friendly, low sodium or ideas for traveling. Frequently participants reported if the required daily amount of fish (6 ounces) was incorporated into salads or casseroles, it resulted in serving size(s) that were not realistic and practical to consume in one meal. This also became problematic with family portions.

Of the eight participants who finished the trial, seven participants completed the intervention during the Thanksgiving or Christmas holiday when family gatherings, traveling and traditional meals are emphasized and treasured. Participants were honest with their brief slip in adherence in their pill diaries and during monthly phone conversations. The holiday season may have contributed to participants' biases while attempting to measure their adherence patterns and potential feasibility.

The use of oral supplementation or dietary omega-3 fatty acids may be promising as an intervention to decrease the risk of breast cancer development. End-of-study patient-reported outcomes provide data about adherence patterns, symptom profiles, and the realistic practicality and feasibility of the intervention. Should dietary intake of omega-3 fatty acids prove to be superior to oral supplementation, innovative recipes will need to be provided that promote sustained adherence and satisfaction, including family preparations. Referral to a clinical dietician may be helpful. Further studies must also address new mechanisms to evaluate the patient's understanding of omega-3 fatty acid intake and their real-life situation of being at high risk for cancer.

Limitations

The small number of participants who completed the trial limits the ability to appropriately analyze the patient reported outcome measures. The small sample size of OSU-10024 also makes it difficult to make generalizations among women with a personal high risk profile and their perceived ability to adhere to a short-term intervention of omega-3 fatty acids. A modifiable limitation regarding the questionnaire involves the wording and style of questions on the 13-item self-reported survey questionnaire administered at the end-of-study appointment. A few of the survey items may have been worded in a manner that led participants to choose a particular answer such as, “was the smell of the salmon bothersome?”

While conducting the monthly nurse phone calls to solicit overall tolerance, adherence and symptom experience, one participant neglected to return any follow up phone calls; therefore, monthly evaluation of the intervention had to be conducted at the participant’s next appointment. This may have caused the participant to forget symptoms or details regarding the intervention that may have been helpful for the end-of-study evaluation.

Implications for Nursing

Few studies to date have investigated the predicted long-term feasibility and realistic practicality of dietary interventions among the participants who may benefit from the intervention. According to the Goal Setting Theory, active patient participation and feedback may guide the decisions of healthcare workers during the development of a sound lifestyle intervention (Bandura, 2004; Locke & Latham, 2002). Although dietary recommendations can, and are directed to a certain population, adherence cannot be guaranteed without first customizing the intervention to the individual patient’s needs and lifestyle. Advances in knowledge of how the human genome acts in collaboration with specific food constituents are useless without taking into consideration how to modify public recommendations to cater to cultural food preferences, taste preferences and food tolerance (Ross, 2010). Nurses, because of the therapeutic and trustworthy bond that is often established with participants, are urged to increase their participation in the health promotion spotlight by leading evaluation strategies (Van Meijel, 2003).

Interim evaluation of the data collected from the ten participants who completed the trial thus far has allowed us to implement an individualized approach to the participants' assigned regimen. Without the implementation of this end-of-study questionnaire, valuable information about the realistic practicality of the intervention would be lost. Measuring patient-reported outcomes has allowed us to gain insight about the daily routine and common obstacles the participants face when implementing a significant dietary change. Analysis of what each participant has achieved through the proposed regimen will boost the confidence of not only the individual involved but also the nurse (Bandura, 2004). The more confident the nurse feels about the efficacy of the intervention, the more likely the patients will benefit from their enthusiasm and potentially be more inclined to adhere to the proposed regimen.

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Appendix

End of Study Questionnaire

Study Title: Omega 3 Fatty Acids and Breast Cancer Prevention:
Protective Benefits of Increased Fish Consumption

Principal Investigator: *Lisa D. Yee*

1. Rate your feeling of accomplishment with this study (Circle one).
 0 1 2 3 4 5 6 7 8 9 10
2. How would you rate your ability to adhere to the requirements of the study (Circle one).
 0 1 2 3 4 5 6 7 8 9 10
3. Taking fish oil capsules or eating the required amount of fish per day was difficult to incorporate in my daily schedule (Circle one)
 Yes No
 Explain _____

4. I would have rather been assigned the other arm of the study (either eating fish or fish oil capsules).
 Yes No
5. **I was assigned to the fish oil capsules** and can picture myself adhering to a similar pill schedule for the rest of my life (Circle one)
 Yes No
6. **I was assigned to the fish cans** and can picture myself adhering to a similar amount of omega3 fish intake for the rest of my life (Circle one)
 Yes No
7. I can picture myself adhering to a combination of supplemental fish oil (capsules) and omega 3 fish for the rest of my life (Circle one)
 Yes No
8. If you were assigned to the fish cans, what were some of your favorite ways to prepare the fish?

9. If you were assigned to the fish cans, was the smell of fish during preparation bothersome?
 (Circle one)

Yes

No

10. List any negative symptoms or side effects that you experienced from your assigned regimen.

11. If you were assigned the fish regimen, did you have to eat differently than your family members during group meals? (Circle one)

Yes

No

N/A

12. If you were assigned the fish regimen, can you picture your family eating omega 3 fish on a regular basis? (Circle one)

Yes

No

N/A

13. Please list any additional thoughts or comments regarding the three month study.

We appreciate your feedback! Thank you for your contribution to breast cancer research!